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REMARKS

The specification has been amended such that the proposed drawing changes should not be required. Claims 1, 5, 6, 8 and 11 have also been amended to overcome the objections under 35 USC §112, second paragraph.

Regarding the Information Disclosure Statements, Applicants submitted four Information Disclosure Statements (March 5, 2002; May 9, 2002; June 18, 2002; and July 8, 2003). Apparently, as the Examiner has suggested, the May 9, 2002 Information Disclosure Statements may have been entered twice by a clerk at the Patent Office.

Claims 1, 2, 5, 11 and 15 stand rejected under 35 U.S.C. §102(b) over Interventional Thermodynamics, Inc. (WO 92/20290 - "WIPO"). The apparatus and methods set forth in this reference differ significantly from that disclosed and claimed by Applicants. For one, WIPO resides in a device and technique for thermally ablating a hollow body organ such as a gall bladder, uterus, appendix, kidney, and the like. (Page 4, line 35, to page 5, line 1.) Although the device of the '290 application does disclose an expandable structure upon which there is disposed a plurality of thermal sensors, the sensors are not intended to measure naturally thermally elevated tissues, but instead, are intended to measure artificially heated tissues to ensure that they are not overheated.

Reference is made to pages 18-20 of the WIPO document, where the operation of the device is explained, including the disclosure that "the power to the heating coil 40 will be controlled to achieve a desired temperature, based on the temperature sensors 32 and/or 61. Usually, the fluid temperature will be in the range from about 53°C to 60°C." (Page 20, lines 23-26.) These temperatures are well above body temperature, even when slightly inflated due to inflamed tissue. A temperature of 53°C is equal to 127.4°F, and 60°C is equal to 140°F.

In distinguishable contrast, Applicants' sensing system is intended to measure physiologic temperatures slightly elevated above normal body temperature, generally on the order of a few degrees or less. Moreover, and importantly, a user of Applicants' apparatus wants to know the degree to which the temperature is elevated, since the localized heating may be indicative of vulnerable plaque or other condition which may lead to a clinical event. For that reason, Applicants' claim 1 includes the limitation of "a data unit operative to receive electrical signals from the temperature sensors and display information indicative of the physiologic [vessel wall] temperature of the vessel wall (as amended)."

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The WIPO reference includes no such teaching, or the desirability or need for such a feature. Instead, the thermal sensors of the WIPO unit are presumably attached to the ablation unit by way of a feedback loop, such that as long as the tissue does not get "too hot," a user would not care about actual temperature elevation, let alone a subtle physiologic change. This conclusion is supported by the language "[u]sually, the fluid temperature will be in the range from about 53°C to 60°C." (Page 20, lines 23-26, emphasis added.) Give the large range in temperature with *might* occur, there is clearly no need for a readout of actual temperature.

Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Systems, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." Connell v. Sears, Roebuck Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Based upon this well-settled precedent, anticipation is expressly precluded. Note that although claim 1 has been modified to recite "information indicative of the physiologic [vessel wall] temperature of the vessel wall," this was done only to clarify that the vessel is not artificially heated, an aspect that should be apparent from the claim as originally submitted. Accordingly, such language will be deleted to expedite allowance should the Examiner believe that the clarification warrants a new search.

Claims 1, 5, 11 and 15 stand rejected under 35 U.S.C. §102(e) over Heuser ('310). Submitted herewith an Affidavit of the named inventor, Mr. Thomas Haddock, indicating that at least the active control limitations set forth in claim 1 were conceived of prior to the filing date of Heuser, followed by diligent reduction to practice, culminating in the filing of the instant application. Accordingly, under 37 C.F.R. §1.131, Heuser is eliminated as a prior-art reference.

Claims 3 and 12 stand rejected under 35 U.S.C. §103(a) over Interventional Thermodynamics in view of Naghavi et al. Claim 3 includes the limitation that the presentation elements are thermally insulative so that the sensors are isolated from temperature fluctuations caused by blood flow or other ambient conditions. Claim 12 includes the limitation of at least one thermal sensor used to measure a

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non-wall temperature. The Examiner concedes that the '290 application is silent on these aspects, but argues that it would have been obvious to use a thermally insulative material in view of Naghavi et al., or to include an "extra" temperature sensor to simultaneously measure the temperature of body fluids in the vicinity of the organ wall.

Applicants respectfully disagree. It is well settled that in order to render a claim obvious, there must be a reason why one having ordinary skill in the pertinent art would have been led to combine references to arrive at Applicants' claimed invention. There must be something *in the prior art* that suggests the proposed modification, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner is also required to make specific findings on a suggestion to combine prior art references. In Re Dembeczak, 175 F.3d 994, 1000-01, 50 USPQ2d 1614, 1617-19 (Fed. Cir. 1999). In addition, a combination of references must not defeat the intended purpose of a prior-art invention, nor must the prior-art invention teach away from the proposed combination.

In this case, the teachings of the '290 application clearly indicate that the use of an insulator would defeat the purposes of the Interventional Dynamics system, since the most accurate reading of the temperature of the tissue being ablated is a primary goal. The same holds true for the inclusion of a temperature sensor intended to read a non-wall temperature, since the Interventional Dynamics application is not concerned with blood flow, but rather, with destroying tissue, such that the measurement of a non-wall temperature would be immaterial.

Claims 2, 3 and 12 stand rejected under 35 U.S.C. §103(a) over Heuser in view of Naghavi. Without presenting available arguments on the merits of this rejection, given that Heuser has been removed as a prior-art reference, these claims are allowable over the Heuser/Hagahavi et al. combination.

Applicants wish to thank the Examiner for participating in a video interview held on March 26, 2003. The allowability of claims 6-10, 13 and 14 has been duly noted.

Attached is a version showing the changes made to the Specification and the amended claims.

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Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADEIN THE SPECIFICATION:*Page 13, lines 9-17:*

Figure 1A shows this embodiment with the padded fingers in an expanded configuration to detect unstable plaque 104 on the wall of a vessel 102. Preferably, the pads 108 connect to cantilevered arms 110 which pivot at a point 112. The point 112, in turn, as connected to a central guide 114 which carries wires 116 to the sensors 106. Figure 1B shows the distal end of the arrangement in a collapsed state, that is, wherein the pads 108 are pivoted down toward one another, allowing the device to be compacted into a compressed form for insertion into a region to be probed. Having found an area to be examined, the pads are expanded gently at various positions to take measurements of the opposite inner walls of a vessel lumen, as shown in Figure 1A.

Page 16, lines 11-18:

As with the other embodiments disclosed herein, preferably the materials 302 forming the arms in this case are insulated against blood flow temperature variations so that the sensors 304 accurately record wall temperatures without being adversely affected by blood flow. This embodiment is also not restricted to the use of two fingers, but more may be used such as the three fingers 310, each with a sensor 312, as shown in Figure 3C. In addition, as with the other embodiments described herein, the embodiment described with reference to Figures 3A through 3C may also be calibrated so as to provide a user with an estimate of inner vessel diameter as well as localized temperature.

Page 16, line 19 to page 17, line 4:

Figures 4A through 4D preferred hand-type embodiments of the invention. In Figure 4A, a sensing head 402 includes one or more sensing cantilevered arms 404, each with a thermal sensor 406, surrounding a central member 410. The arms and central member are configured such that when the member is pulled from the proximal end, the arms fan outwardly from the contracted state of Figure 4A into a the expanded position, as shown in Figure 4B. Again, the arms are cantilevered to provide a relatively constant and uniform force against the vessel wall in the expanded state while avoiding excess

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pressure.

Page 17, lines 5-12:

In Figures 4A and 4B, the member 410 is preferably not uniform in cross section but, rather, includes a conical or ramp shape along the distal end of the member, such that when it is pulled from the proximal end the arms fan outwardly and into the sensing position shown in Figure 4B. Figure 4D is a drawing of a central lumen configuration incorporating an inner lip providing a rapid yet controlled flare of the expanding arms. In this case the proximal end of the plunger 440 includes a rim 442 [422] configured to lock into a corresponding recess 444 in the body of the sheath. This allows the arms to expand outwardly while preventing over-expansion.

IN THE CLAIMS:

1. (Twice Amended) A system for sensing the temperature of a vessel wall [, including] or an arterial wall, the system comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including one or more presentation elements, each element having a temperature sensor supported thereon;

each presentation element having a proximal end coupled to the distal end of the catheter and a distal end coupled to the distally protruding end of the filament such that pulling on the manually operated expansion control causes each element to move from a retracted position to an expanded position enabling the sensor to be placed in contact or immediately proximate to the vessel wall, and pushing on the manually operated expansion control causes each presentation element to return to the retracted position from the expanded position; and

a data unit operative to receive electrical signals from the temperature sensors and display information indicative of the physiologic [vessel wall] temperature of the vessel wall.

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5. (Twice Amended) The system of claim 1, wherein the presentation elements are configured such that blood [may continue] continues to flow around the elements when the elements are in the expanded position.

6. (Twice Amended) A system for sensing the temperature of the wall of a vessel including an arterial wall, comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including a plurality of presentation elements in the form of cantilevered fingers at the distal end of the catheter which expand outwardly by pulling on the manually operated expansion control, each element having a temperature sensor supported thereon which is adapted to be placed in contact or immediately proximate to the vessel wall during the expansion; and

a data unit operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors.

8. (Twice Amended) The system of claim 6, wherein the fingers surround a central plunger coupled to the manually operated expansion control, such that pulling on the plunger causes the fingers to expand outwardly and pushing on the plunger causes the fingers [finger] to turn to a contracted position.

11. (Twice Amended) The system of claim 1, wherein the temperature sensing tip features a plurality of longitudinal slices forming a basket[-like] structure which flares out when the manually operated expansion control is pulled, and which collapses when the control is pushed.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Haddock et al.

Serial No.: 09/882,889

Group No.: 3736

Filed: June 15, 2001

Examiner: C. Marmor II

For: TEMPERATURE SENSING CATHETER

**AFFIDAVIT OF THOMAS F. HADDOCK
UNDER 37 CFR §1.131**

I, Thomas F. Haddock, make the following statements from my own personal knowledge and experience under penalty of perjury:

1. I am the named inventor on U.S. Patent Application Serial No. 09/882,889.
2. I understand that some of the claims of this application have been rejected over Heuser, published U.S. Patent Application No. US 2002/0048310 A1.
3. It is my further understanding that the '310 application to Heuser was filed November 5, 2001, and is based upon a previous application bearing Serial No. 09/521,091, filed March 7, 2000.
4. Submitted herewith are two invention disclosure information forms which I filled out, signed and submitted to my former employer, Accumed Systems, Inc. prior to the earliest filing date of the Heuser applications. The first disclosure, a copy of which is attached hereto, is entitled "Expanding Padded Thermal Sensors," and the second disclosure submitted herewith is entitled "Adaptation of Expanded Padded Thermal Sensors." Although the dates have been obscured to maintain our actual date of conception in confidence, I hereby affirmatively state that these documents, and the embodiments disclosed in these invention disclosure forms were conceived of prior to March 7, 2000. I diligently reduced these ideas to practice, culminating in the filing of the '889 application on June 15, 2001, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/211,995, filed June 16, 2000.

FURTHER AFFIANT SAYETH NOT.

Date: Mar 21, '03


THOMAS F. HADDOCK